



UNITED STATES PATENT AND TRADEMARK OFFICE

AT

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,753	10/29/2001	Yasuhiro Sakai	3029-74	7298

7590 04/02/2004

Lance J. Lieberman, Esq.
Cohen, Pontani, Lieberman & Pavane
551 Fifth Avenue, Suite 1210
New York, NY 10176

EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
10/005,753Applicant(s)
SAKAI ET AL.

Examiner

Francisco C Prats

Art Unit

1651

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) The period for reply expires ____ months from the mailing date of the final rejection.
b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. Applicant's reply has overcome the following rejection(s): _____.
4. Newly proposed or amended claim(s) ____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 20-29.

Claim(s) withdrawn from consideration: _____.

8. The drawing correction filed on ____ is a)a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. Other: _____.

ATTACHMENT TO ADVISORY ACTION

The after-final amendment filed March 15, 2004, has been received and will be entered upon the filing of a notice of appeal.

New claim 29 will be included in all of the pending grounds of rejection.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 9, 2004, has not been considered. It is noted that the required fee has been paid. However, the statement provided by applicant contains **both** the statement under 37 CFR 1.97(e) (1) **and** the statement under 37 CFR 1.97(e) (2). These statements are entirely contradictory.

Specifically, 37 CFR 1.97(e) reads as follows (emphasis added) :

(e) A statement under this section must state **either**:

(1) That **each item** of information contained in the information disclosure statement **was** first **cited** in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; **or**

(2) That **no item** of information contained in the information disclosure statement **was cited** in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry,

no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

Thus, 37 CFR 1.97 requires that applicant make one or the other of the statements under subsection (e), but not both. This is clear by the mutually exclusive language of the two subsections of 1.97(e). However, on the current record, applicant has stated **both** that

(1) the cited prior art "was first cited in [a] communication from a foreign patent office in a counterpart foreign application" **and** that

(2) "no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application."

Thus, applicant's statement includes averments which are entirely contradictory. Moreover, it is not clear how applicant can properly make the statement under 37 CFR 1.97(e) (2), since that statement requires no knowledge of any of the cited documents more than three months before the IDS was filed. Specifically, EP 1 136 563 A2, cited in the IDS filed February 9, 2004, lists as inventors two of the inventors in this application. Thus, applicant clearly knew of this document more than three months before the IDS was filed. In view of the

inconsistencies in the filing of the IDS of February 9, 2004, the IDS has not been considered. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

All of applicant's argument regarding the pending grounds of rejection has been fully considered but is not persuasive of error. Applicant's argument regarding the rejection under § 102 ignores the breadth of the current claim language. At its broadest, the claim language "for maintaining acidity" can be construed as simply requiring buffering capacity at any pH, since pH is a measure of the hydrogen ion concentration in a solution, which is a measure of acidity. Thus, at their broadest, the claims encompass the use of any buffer. Even construing "acidity" to mean only those pH values below 7.0, the page from the Sigma Catalog, Exhibit 1, does not demonstrate

that Tris cannot be used to buffer such solutions. Official notice is taken of the fact that Tris is in fact useful as a buffer at pH values below 7.0, and has been so used on a multitude of occasions, many of which appear in the U.S. patent literature. Applicant's argument, that Tris is not a "buffer for maintaining acidity", is factually incorrect.

The claim language "for maintaining acidity" can also be construed as a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). As discussed immediately above, official notice is taken of the fact that Tris was known to be useful, and had in fact been used, as a buffer at pH values below 7.0, which is well within the definition of the term "acidity."

Similarly, with respect to the argument that claim 20 recites a "staining" solution, the fact remains that the prior art solution contains all of the claimed ingredients, and can in

fact be used to stain bacteria. Applicant's arguments with respect to the intended use of the claimed composition do not serve to distinguish the claimed composition over the prior art. This is also true with respect to newly submitted claim 29. The anticipation rejection must be maintained.

With respect to the issue of obviousness, it is again pointed out that Jackson's solution must be considered a "staining solution," because it contains all of the ingredients required by applicant's claims. If some other agent is required for something to be a "staining solution", then that agent should be recited in the claims. It is also noted, as argued by applicant, that Jackson's solution is a urease assay solution whereas the intended use of the claimed solution is as a direct bacterial stain. However, applicant's claims are not directed to staining methods. Rather, applicant's claims are directed to compositions comprising certain specific ingredients. Because the prior art discloses and provides motivation for combining those ingredients, the claims do not distinguish over the prior art.

With respect to the various pH ranges and dyes recited in dependent claims, it is noted at the outset that none of these allegedly critical limitations appears in an independent claim. It is also noted that a restriction has been made, and that

Art Unit: 1651

prosecution is technically limited to that elected invention. Thus, the limitations with respect to pH ranges and suitable dyes are only considered to the extent they fall within the context of the elected species of invention, i.e., a composition containing sulfamic acid. With respect to Jackson's disclosure, it is noted that the dye used therein, bromophenol blue, is a pH indicator. However, because applicant's claim 24 encompasses pH values as high as 5.5, which would have been suitable for use in the assays disclosed by Jackson, that claim cannot be considered free of the prior art. As for evidence to support this assertion, one need only consult the cited patent. The urease assay described in Jackson measures a change in pH from 6.8 to 9. See column 1, lines 57-67. One of ordinary skill clearly would have recognized that the color change in the assay described by Jackson could have been suitably read using a buffer having a pKa of 5.5, since that pH would have been low enough to allow for the color change to occur, yet not too low to eliminate urease activity. Therefore, claim 24 remains properly rejected because the claim encompasses the use of buffers suitable for Jackson's assay.

It is noted, as argued by applicant, that claim 25 recites pH values of 2.0 to 3.0, which do not appear to be suggested in Jackson's process. However, nowhere are applicant's claims

limited to a single embodiment reciting a composition comprising a bacterial dye, sulfamic acid, and a buffer at pH 2.0 to 3.0. Thus, while such a combination of ingredients might be considered free of the prior art, the current claim language does not provide a single embodiment containing the combination of limitations required for allowance of the claims.

With respect to the use of specific dyes, it is again respectfully pointed out that the limitations with respect to pH ranges and suitable dyes are only considered to the extent they fall within the context of the elected species of invention, i.e., a composition containing sulfamic acid. On the current record, official notice is taken of the fact that fluorescent pH indicators, such as the compounds fluorescein or 4-methylumbelliferoine, were well known in the art at the time of applicant's invention, and that therefore their use in the reagent disclosed by Jackson would have been an obvious substitution of one equivalent pH indicating dye for another, as asserted in the final rejection. If applicant still desires evidence that fluorescein or other fluorescent pH indicators were well known in the art, then such evidence, such as a Merck Index listing, can be provided.

Similarly, with respect to the use of different surfactants including those recited in the claims, it is a well-established

tenet of patent law that substitution of one equivalent element for another is considered obvious, absent some demonstration that the substitution achieves some unexpected result. See MPEP § 2144.06, subsection entitled "SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE." In the instant case, the prior art suggests the use of surfactants in the urease assay. Applicant's claims recite the use of surfactants in claims which encompass the compositions used in the prior art urease assay. Because the claimed surfactants and the prior art surfactants possess the common property of surface activity, one of ordinary skill would have recognized their equivalency. The fact that applicant's purpose for adding the surfactant is different than the purpose in the prior art is irrelevant, as long as the prior art suggests practicing the claimed invention. See MPEP § 2144, subsection, entitled "RATIONALE DIFFERENT FROM APPLICANT'S IS PERMISSIBLE."

As pointed out by applicant, no prior art suggests that polymethine dyes would have been suitable in the processes disclosed by Jackson. Still, nowhere are applicant's claims limited to a single embodiment reciting a bacterial staining composition comprising a polymethine dye, sulfamic acid, and a buffer at an acidic pH. Thus, as discussed above, while such a combination of ingredients might be considered free of the prior

art, the current claim language does not provide a single embodiment containing the combination of limitations required for allowance of the claims.

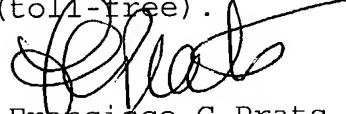
In sum, for the reasons set forth above, the claims presently fail to recite a single embodiment which distinguishes them from the cited prior art. The rejections of record must therefore be maintained.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C Prats
Primary Examiner
Art Unit 1651

FCP